510(k) Summary
for the Visual Footcare Technologies, LLC
TempStat™

JUN 2 4 2008

1. SUBMITTER/510(K) HOLDER

Visual Footcare Technologies, LLC
23 Split Rock Road
Pound Ridge, NY 10576

Contact Person: Scott R. Kantro, DPM
Telephone: (914) 588-8808
Email: skantro@visualfootcare.com

Date Prepared: June 2, 2008

2. DEVICE NAME

Proprietary Name: Visual Footcare Technologies, LLC TempStat™
Common/Usual Name: Examination Mirror
Classification Name: Daily activity assist device

3. PREDICATE DEVICES

- 890.5050 Daily Activity Assist Device Class I (General Controls)
- The Fred Sammons Extend-A-Mirror (K760293, Product Code ILW).
- 880.2200 Liquid Crystal Forehead Temperature Strip Class II (Special Controls) LCR-Hallcrest FeverScan™ Forehead Strip Thermometer

4. DEVICE DESCRIPTION

The Visual Footcare Technologies TempStat™ device is a daily activity assist designed to make the examination of the plantar surface of the foot simple and easy to accomplish. It consists of a plastic panel that has a 2X convex mirror in the center third section, with two polycarbonate plastic pads on either side of the mirror. The plastic pads are contructed primarily of liquid crystalline cholesteric esters that react to skin surface temperature and change to a specific color relative to that level of temperature. With this device, the patient can visually examine his foot and also see a graphical representation of the heat pattern on the plantar sole of his foot. The device is designed

to sit on the floor in front of the patient, who is seated in a chair. The patient leans over and raises his foot to see the bottom of his foot in the mirror, and then places them on the polycarbonate pads. After 60 seconds, the patient can remove his feet and can visualize the pattern of skin temperature from the plantar surface of his foot.

5. INTENDED USE

TempStat™ is a daily activity assist device that is intended to assist a patient to visualize the image and condition of the soles of their feet in connection with a daily self-examination for signs of inflammation on the sole of the foot. TempStat™ will assist the patient in determining when they should contact their healthcare provider for further diagnosis and treatment regarding any skin changes seen by a mirror and/or highlighted by the liquid crystal foot pads. TempStat™ is intended to be used as an adjunct to, and not in replacement of, periodic foot care and examinations conducted by a health care professional and used under the direction of a health care professional and does not diagnose any specific disease state.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Visual Footcare Technologies TempStat™ device is similar in design and method of operation to the Fred Sammons, Inc. Extend-A-Mirror (K760293). Both devices use a mirror to allow the user to visualize the plantar surface of their feet.

The TempStat™ device is also similar in design and method of operation to the LCR-Hallcrest FeverScan™ Forehead Strip Thermometer. Both devices employ liquid crystals encased within polycarbonate plastic. The liquid crystals change color corresponding to the skin temperature they are in contact with. In fact, the manufacturer of the LCR-Hallcrest FeverScan™ also manufactures the pads used in the TempStat™ device.

7. PERFORMANCE TESTING

The temperature accuracy of the TempStat™ device was assessed as specified in Section 5.2 of the ASTM E 1061-01 Standard. The results demonstrated that the TempStat™ liquid crystal pads are accurate within 1°F with respect to color changes.

Visual Footcare Technologies, LLC, conducted a patient preference study to assess the ability of the TempStat™ device to provide assistance to the subject in visualizing the plantar surface of his foot. All study subjects felt that the TempStat™ device enhanced their ability to visualize the plantar surface of their feet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2008

Mr. Andrew Singer
President
Visual Footcare Technologies, LLC
P.O. Box 760
South Salem, New York 10590

Re: K080816
Trade/Device Name: Visual Footcare Technologies, LLC, TempStat™ Device
Regulation Number: 21 CFR 890.5050
Regulation Name: Daily Activity Assist Device
Regulatory Class: I
Product Code: OIZ
Dated: June 2, 2008
Received: June 3, 2008

Dear Ms. Singer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

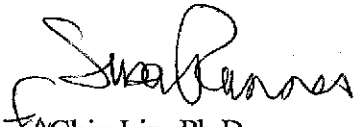
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080816

Device Name: Visual Footcare Technologies, LLC, TempStat™ Device

Indications for Use:

TempStat™ is a daily activity assist device that is intended to assist a patient to visualize the image and condition of the soles of their feet in connection with a daily self-examination for signs of inflammation on the sole of the foot. TempStat™ will assist the patient in determining when they should contact their healthcare provider for further diagnosis and treatment regarding any skin changes seen by a mirror and/or highlighted by the liquid crystal foot pads. TempStat™ is intended to be used as an adjunct to, and not in replacement of, periodic foot care and examinations conducted by a health care professional and used under the direction of a health care professional and does not diagnose any specific disease state.

Prescription Use __X__ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080816